APR - 7 2010

OMNIlife science™

510(K) SUMMARY K090845

Apex ARC™ Hip Stem

April 7, 2010

1. Submitter

OMNI life science, Inc
50 O'Connell Way
E. Taunton, MA 02718

Contact: Robert Zoletti
VP Regulatory Affairs
774-226-1845

2. Device Name

Proprietary Name: Apex ARC™ Hip Stem
Common Name: Hip prosthesis, uncemented
Classification Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II per 21 CFR §888.3353 and §888.3358
Product Codes: LZO, MEH, and LPH

3. Legally Marketed Predicate Device

K041950 - Apex K2,
K071946, K083495 - Aesculap Metha®

4. Device Description

The Apex ARC Hip Stem consists of a curved, rectangular tapered stem, and modular necks that connect to the tapered hole in the stem. The femoral stems are manufactured from titanium alloy and the modular necks are manufactured from cobalt chromium alloy. Three neck sizes are offered, with a neutral, 8 degree, and 12 degree varus-valgus angle, respectively. The necks are compatible with the modular heads that are part of the Apex Modular and Apex K2 hip systems (K000788, K012918, and K073150) and may be used with head diameters and offsets up to a maximum offset of +7 mm. These configurations allow the user to choose a combination of stem, neck, and head components to appropriately fit the anatomy of the patient. The Apex ARC Hip Stem may be used in conjunction with the Apex Modular™ Acetabular Cup (K031110, K062489, and K073150) for total hip arthroplasty.

5. Intended Use

The Apex ARC™ Hip Stem is intended for use as the femoral component of a primary or revision total hip replacement. This femoral hip stem is intended for uncemented fixation and single use implantation. This prosthesis may be used for the following conditions, as appropriate:

- Non-inflammatory degenerative joint disease, including osteoarthritis and avascular necrosis;
- Rheumatoid arthritis;
- Correction of functional deformity;
  Congenital dislocation;
- Revision procedures where other treatments or devices have failed;
- Femoral neck and trochanteric fractures of the proximal femur.

6. Predicate Device Comparison

Substantial equivalence is claimed to the Apex K2™ Hip System (distributed by OMNI life science, Inc.) and the Metha® Hip System (distributed by Aesculap Implant Systems, Inc.). The table below compares the features and characteristics of the Apex ARC Hip Stem to these predicate devices:

	Apex ARC™	Apex K2™	Aesculap Metha®
FDA 510(k)'s		K041950	K071916 and K083495
INTENDED USE			
Primary and revision hip replacement, non-cemented	Yes	Yes	Yes
DESIGN			
Circumferential porous coating	Yes – plasma sprayed CP Ti	Yes – plasma sprayed CP Ti	Yes – plasma sprayed CP Ti
Proximal coating (only)	Yes	Yes	Yes
Modular head	Yes	Yes	Yes
Modular neck	Yes	Yes	Yes
Tapered stem	Yes	Yes	Yes
Cross-sectional shape	Rectangular	Rectangular	Rectangular/ rounded
Distal slot(s)	Yes	No	No
Distal flutes	No	No	No
MATERIALS			
Titanium alloy (Ti6Al4V) stem	Yes	Yes	Yes
Cobalt chromium modular neck	Yes	No – titanium alloy	Yes
Cobalt chromium or alumina ceramic heads	Yes (both)	Yes (both)	Yes (both)
Titanium porous coating	Yes - unalloyed	Yes - unalloyed	Yes – unalloyed
Hydroxyapatite overcoat option	Yes	No	Yes – calcium phosphate

The most significant difference between these devices is that the subject Apex ARC hip stem and the predicate Aesculap Metha hip stem both employ cobalt chromium modular necks with a tapered junction between the neck and the stem, whereas the Apex K2 stem system employs titanium alloy modular necks with a cylindrical press-fit junction and alignment pin.

7. Non-Clinical Test Summary

The following tests were conducted:

- Distal fatigue strength per ISO 7206-4:1989, ISO 7206-8:1992, and ASTM 2068-09.
- Fretting potential per ISO 17853:2003.
- Disassembly strength after fatigue testing per ASTM F2009-00.
- Proximal fatigue strength per ISO 7206-6:1992 and ASTM 2068-09.
- Torsional strength of the modular neck.
- Range of motion per ISO 21535:2007.
- Burst test, fatigue test, post-fatigue burst test, pull-off, and rotational stability of the worst case modular neck-ceramic head combination per FDA *Guidance for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems*, and ISO 7206-10:2003.
- ETO Residuals per ANSI/AAMI/ISO 10993-7.
- The Hydroxyapatite coating was previously cleared in K043123

8. Clinical Test Summary

No clinical studies were performed.

9. Conclusions Nonclinical and Clinical

The Apex ARC™ is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

OMNI life science, Inc.
% Mr. Robert Zoletti
Vice President Regulatory Affairs
50 O'Connell Way
E. Taunton, Massachusetts 02718

APR - 7 2010

Re: K090845
Trade/Device Name: Apex ARC™ Hip Stem
Regulation Number: 21 CFR 8888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prothesis
Regulatory Class: II
Product Code: LZO, MEH, LPH
Dated: March 31, 2010
Received: April 1, 2010

Dear Mr. Zoletti:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K090845

Device Name: Apex ARC™ Hip Stem

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Prescription Use__X____ AND/OR Over-The-Counter Use_____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K090845